

10/553163

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QUEEN THOMAS  
Printed NameQueen Thomas  
Signature

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

U.S. National Phase Of International Appl. No. PCT/US2004/010960

International Filing Date: April 22, 2004

First Applicant: DiMarchi, Richard et al.

For: INSULIN ANALOGS HAVING PROTRACTED TIME ACTION

Docket No.: X-16270M

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

As a means of complying with the duty of disclosure, Applicants submit an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) and provides a copy of each of the listed documents for consideration by the Examiner.

Since this Statement is being filed in accordance with 37 C.F.R. 1.97(b), Applicants submit that no additional fee is required.

Applicants request consideration of this information.

Respectfully submitted,

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OCTOBER 13, 2005

FORM PTO 1449 (modified)	Atty. Docket No. X-16270M	U.S. National Phase of International Application No. PCT/US04/10960 <b>10/553163</b>
	Applicants Kohn, et al.	
	International Filing Date April 22, 2004	Group

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Pages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US 3,528,960	09-15-1970	Haas, <i>et al.</i>	
	AB	US 3,864,325	02-04-1975	Smyth	
	AC	US 3,868,356	02-25-1975	Smyth	
	AD	US 3,868,357	02-25-1975	Smyth	
	AE	US 3,869,437	03-04-1975	Lindsay, <i>et al.</i>	
	AF	US 3,950,517	04-13-1976	Lindsay, <i>et al.</i>	
	AG	US 5,015,728	05-14-1991	Obermeier, <i>et al.</i>	
	AH	US 5,149,716	09-22-1992	Vertesy, <i>et al.</i>	
	AI	US 5,177,058	01-05-1993	Dorschug	
	AJ	US 5,430,016	07-04-1995	Balschmidt, <i>et al.</i>	
	AK	US 5,466,666	11-14-1995	Obermeier, <i>et al.</i>	
	AL	US 5,491,296	02-13-1996	Bergemann	
	AM	US 5,506,202	04-09-1996	Vertesy, <i>et al.</i>	
	AN	US 5,656,722	08-12-1997	Dorschug	
	AO	US 5,698,669	12-16-1997	Hoffmann, <i>et al.</i>	
	AP	US 6,100,376	08-08-2000	Dorschug	
	AQ	US 6,323,311	11-27-2001	Liu, <i>et al.</i>	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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FORM PTO 1449 (modified)	Atty. Docket No. X-16270M	U.S. National Phase of International Application No. PCT/US04/10960
	Applicants Kohn, et al.	
	International Filing Date April 22, 2004	Group

	AR	US 6,444,641	09-03-2002	Flora	
	AS	US 6,221,837	04-24-2001	Ertl, et al.	
	AT	US 6,531,448	03-11-2003	Brader	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number 4- Kind Code <sup>5</sup> (if known)				
	BA	GB 1 415 333	11-26-1975	Schering Aktiengesellschaft		
	BB	EP 254 516	01-27-1988	Markussen, <i>et al.</i>		
	BC	EP 280 534	08-31-1988	Langkjaer, <i>et al.</i>		
	BD	WO 89/10937	11-16-1989	Brange, <i>et al.</i>		
	BE	EP 390 327	10-03-1990	Prouty		
	BF	WO 98/05361	02-12-1998	Fridkin, <i>et al.</i>		
	BG	WO 03/20201	03-13-2003	DeFelippis, <i>et al.</i>		
	BH	WO 00/64940	11-02-2000	Brader, <i>et al.</i>		
	BI	WO 01/00674	01-04-2001	DeFelippis, <i>et al.</i>		
	BJ	WO 01/00675	01-04-2001	Brader		
	BK	WO 99/21573	05-06-1999	Flora		
	BL	WO 03/53339	07-03-2003	Beals, <i>et al.</i>		
	BM	WO 03/53460	07-03-2003	Brader, <i>et al.</i>		
	BN	WO 99/32116	07-01-1999	Brader		

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FORM PTO 1449 (modified)  INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. X-16270M	U.S. National Phase of International Application No. PGT/US04/10960 <b>10/553163</b>
	Applicants Kohn, et al.	
	International Filing Date April 22, 2004	Group

	BO	WO 95/07931	03-23-1995	Havelund, et al.		
	BP	WO 99/21578	05-06-1999	Brader		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T <sup>6</sup>
	CA	MASSEY, D., <i>et al.</i> , "The Effect of Acylation on the Molecular Size of Insulin" <i>Eur. J. Biochem</i> 31:470-473 (1972).	
	CB	MARKUSSEN, J., <i>et al.</i> , "Soluble, prolonged-acting insulin derivatives. I. Degree of protraction and crystallizability of insulins substituted in the terminus of the B-chain," <i>Protein Engineering</i> 1(3):205-213 (1987).	
	CC	MARKUSSEN, J., <i>et al.</i> , "Soluble, prolonged-acting insulin derivatives. II. Degree of protraction and crystallizability of insulins substituted in positions A17, B8, B13, B27 and B30," <i>Protein Engineering</i> 1(3):215-223 (1987).	
	CD	MARKUSSEN, J., <i>et al.</i> , "Soluble, prolonged-acting insulin derivatives. III. Degree of protraction, crystallizability and chemical stability of insulins substituted in positions A21, B13, B23, B27 and B30," <i>Protein Engineering</i> 2(2) 157-166 (1988).	
	CE	MAY, J., <i>et al.</i> , "N <sup>ε</sup> B <sup>29</sup> -(+)-Biotinylinsulin and Its Complexes with Avidin," <i>J. Biol. Chem.</i> 253(3):686-690 (1978).	
	CF	TIETZE, <i>et al.</i> , <i>Biochimica et Biophysica Acta</i> 59:336-346 (1962).	
	CG	WALLACE, G., "Chromatographic analysis of the Trinitrophenyl Derivatives of Insulin," <i>J. Chromatography</i> 427:239-246 (1988).	

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